Policy Number	**SUR701.024**
Policy Effective Date	**12/15/2025**

Surgical Treatments for Breast Cancer-Related Lymphedema

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Disclaimer

Carefully check state regulations and/or the member contract.
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Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0123 (IL HB 1384) Coverage for Reconstructive Services requires the following policies amended, delivered, issued, or renewed on or after January 1, 2025 (Individual and family PPO/HMO/POS; Student; Group [Small Group; Mid-Market; Large Group Fully Insured PPO/HMO/POS] or Medicaid), to provide coverage for medically necessary services that are intended to restore physical appearance on structures of the body damaged by trauma.

EXCEPTION: For HCSC members residing in the state of Arkansas, § 23-99-405 related to coverage of mastectomy and reconstruction services, should an enrollee elect reconstruction after a mastectomy, requires coverage for surgery and reconstruction of the breast on which the mastectomy has been performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, and protheses and coverage for physical complications at all stages of a mastectomy, including lymphedema. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

Coverage

Lymphatic physiologic microsurgery to treat lymphedema (including, but not limited to, lymphatico-lymphatic bypass, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node transplantation, and vascularized lymph node transfer) in individuals who have been treated for breast cancer **is considered experimental, investigational and/or unproven.**

Lymphatic physiologic microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach) in individuals who are being treated for breast cancer **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

Surgery and radiotherapy for breast cancer can lead to lymphedema and are some of the most common causes of secondary lymphedema. There is no cure for lymphedema. However, physiologic microsurgical techniques such as lymphaticovenular anastomosis or vascularized lymph node transfer have been developed that may improve lymphatic circulation, thereby decreasing symptoms and risk of infection. This policy focuses on physiologic microsurgical interventions and will not consider reductive (also known as excisional or ablative) surgical interventions such as liposuction.

Lymphedema
Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. Lymphedema can be caused by congenital or inherited abnormalities in the lymphatic system (primary lymphedema) but is most often caused by acquired damage to the lymphatic system (secondary lymphedema).

Diagnosis and Staging
A diagnosis of secondary lymphedema is based on history (e.g., cancer treatment, trauma) and physical examination (localized, progressive edema and asymmetric limb measurements) when other causes of edema can be excluded. Imaging, such as magnetic resonance imaging, computed tomography, ultrasound, or lymphoscintigraphy, may be used to differentiate lymphedema from other causes of edema in diagnostically challenging cases.

Table 1 lists International Society of Lymphology guidance for staging lymphedema based on "softness" or "firmness" of the limb and the changes with an elevation of the limb. (1)

Table 1. Recommendations for Staging Lymphedema

Stage	Description
Stage 0 (subclinical)	Swelling is not evident, and most individuals are asymptomatic despite impaired lymphatic transport
Stage I (mild)	Accumulation of fluid that subsides (usually within 24 hours) with limb elevation; soft edema that may pit, without evidence of dermal fibrosis
Stage II (moderate)	Does not resolve with limb elevation alone; limb may no longer pit on examination
Stage III (severe)	Lymphostatic elephantiasis; pitting can be absent; skin has trophic changes

Breast Cancer-Related Lymphedema

Breast cancer treatment is one of the most common causes of secondary lymphedema. Both the surgical removal of lymph nodes and radiotherapy are associated with development of lymphedema in individuals with breast cancer.

In a systematic review of 72 studies (N=29,612 women), DiSipio et al. (2013) reported that approximately 1 in 5 women who survive breast cancer will develop arm lymphedema. (2) Reviewers reported that risk factors for development of lymphedema that had a strong level of evidence were extensive surgery (i.e., axillary-lymph-node dissection, greater number of lymph nodes dissected, mastectomy) and being overweight or obese. The incidence of breast cancer-related lymphedema (BCRL) was found by DiSipio et al. as well as other authors to be up to 30% at 3 years after treatment. (2-4)

Studies have also suggested that Black breast cancer survivors are nearly 2.2 times more likely to develop BCRL compared to White breast cancer survivors. (5) These observations may be linked to racial disparities with regards to access to treatment and the types of treatments received. Black women are more likely than White women to undergo axillary lymph node dissection, which is associated with greater morbidity than the less invasive sentinel lymph node biopsy. While this may be explained in part by Black individuals having a higher likelihood of being diagnosed with more aggressive tumors, there is evidence that even when adjusting for stage and grade of tumors, Black women are more likely to undergo axillary lymph node dissection, putting Black women at greater risk of BCRL. Additionally, Black breast cancer survivors, on average, have higher body mass indexes than White breast cancer survivors, which could contribute to development of lymphedema in this setting as well.

Management and Treatment

Early and ongoing treatment of lymphedema is necessary. Conservative therapy may consist of several features depending on the severity of the lymphedema. Individuals are educated on the importance of self-care including hygiene practices to prevent infection, maintaining ideal body weight through diet and exercise, and limb elevation. Compression therapy consists of repeatedly applying padding and bandages or compression garments. Manual lymphatic drainage is a light pressure massage performed by trained physical therapists or by individuals

designed to move fluid from obstructed areas into functioning lymph vessels and lymph nodes. Complete decongestive therapy is a multiphase treatment program involving all of the previously mentioned conservative treatment components at different intensities. Pneumatic compression pumps may also be considered as an adjunct to conservative therapy or as an alternative to self-manual lymphatic drainage in patients who have difficulty performing self-manual lymphatic drainage. In individuals with more advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques such as liposuction may be performed.

Regulatory Status
Physiologic microsurgery for lymphedema is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Physiologic Microsurgery to Treat Lymphedema
Clinical Context and Therapy Purpose
The purpose of physiologic microsurgery treatments for lymphedema in individuals who have been treated for breast cancer is to provide a treatment option that is an improvement on existing therapies such as conservative therapy with compression garments or bandages, manual lymph drainage or pneumatic pumps, and decongestive therapy. Both surgical

treatment and radiotherapy for breast cancer can lead to lymphedema and are some of the most common causes of secondary peripheral lymphedema.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals who have been treated for breast cancer, who have developed secondary lymphedema, and who have insufficient symptom reduction with conservative therapy, who have recurrent cellulitis or lymphangitis, or who are dissatisfied with conservative therapy. Lymphedema in its late chronic phase is irreversible. The surgical techniques of interest in this review are those performed in individuals who have not reached the irreversible stage, i.e., those who have functioning lymphatic channels (stage I, II or early stage III) (Table 1).

Interventions
This policy focuses on physiologic microsurgical interventions; it does not consider reductive (also known as excisional or ablative) surgical interventions (e.g., liposuction). Physiologic microsurgical interventions include several techniques and can be broadly grouped into procedures that 1) reconstruct or bypass the obstructed lymphatic vessels to improve lymphatic drainage and 2) transfer lymph tissue into an obstructed area to reestablish lymphatic flow. Table 2 includes a brief description of the surgeries.

Table 2. Physiologic Microsurgical Interventions for Lymphedema

Purpose	Surgery	Description	Key Features
Bypass or reconstruct obstructed lymph vessels to improve drainage	Lymphatic-lymphatic bypass	Connects functioning lymphatic vessels directly to affected lymphatic vessels; healthy vessels come from donor site	• Lymphedema can develop in donor extremity • Scarring at donor site
	Lymphovenous bypass and lymphaticovenular anastomosis	Lymphatic vessels in an affected limb are connected to the venous system	• Outpatient procedure or usually discharged within a day • Quick return to daily activities
Transfer lymph tissue to reestablish lymphatic flow	Autologous lymph node transplantation and vascularized lymph node transfer	Healthy lymph nodes are transferred to the affected limb	• Inpatient procedure; requires 2 to 3 days of hospitalization

			• Lymphedema can develop in donor extremity

Comparators
Physiological microsurgery may be used as an adjunct to conservative therapy. Conservative therapy is multimodal. It involves meticulous skin hygiene and care, exercise, compression therapy, and physical therapy (manual lymphatic drainage). Complete decongestive therapy and pneumatic compression pumps are also used as adjuncts to conservative therapy.

Outcomes
Objective outcomes of interest include a reduction in limb circumference and/or volume and reduction in the rates of infections (e.g., cellulitis, lymphangitis). Volume is measured using different methods; e.g., tape measurements with geometry formulas, perometry, and water displacement. Bioimpedance spectroscopy may be used to detect changes in tissue fluid accumulation; this technology is reviewed in MED201.036 Bioimpedance Devices for Detection and Management of Lymphedema.

Patient-reported outcomes (PROs) of interest include symptoms, quality of life, and functional measures. A systematic review of PRO instruments and outcomes used to assess quality of life in breast cancer patients with lymphedema found that most studies included generic PRO instruments or oncology PRO instruments. (6) Lymphedema-specific instruments are occasionally used; specifically, the Upper Limb Lymphedema 27 was found to have strong psychometric properties. An additional systematic review of PROs by Coriddi et al. (2020) identified the most commonly used validated scale across 32 studies was the lymph quality of life measure for limb lymphedema (LYMQOL); however, non-validated instruments were used in half of all studies. (7)

There does not appear to be a consensus on minimally clinically important change for either objective outcomes, such as changes in arm volume, or subjective measures, such as changes to patient symptoms or quality of life.

<u>Study Selection Criteria</u>
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Because multiple systematic reviews of studies were available for both classes of microsurgery, the focus is on systematic reviews published in 2015 or later.

Systematic Reviews

Leung et al. (2015) reported on a systematic review of the surgical management of breast cancer-related lymphedema (BCRL). (8) The search included studies reporting on the efficacy of surgical techniques used for the prevention or treatment of BCRL published between 2000 and 2014. Only 1 study on lymphatico-lymphatic bypass was identified and published since 2000. The study included 7 patients followed for 2.6 years. One patient had "complete recovery" as measured by the circumference of the affected limb and the remaining 6 patients had a "reasonable outcome." Postsurgery complications were cellulitis, donor-site lymphorrhea, and transient edema of the donor leg.

Numerous systematic reviews have examined microsurgical interventions involving the venous system, such as lymphaticovenular anastomosis (LVA) or the transplantation of lymphatic tissue, including vascularized lymph node transfer (VLNT). The present review places emphasis on systematic reviews published within the last two years. Meuli et al. (2023) conducted a systematic review and meta-analysis on the efficacy of LVA and VLNT in treating lymphedema, focusing on 150 studies with 6,496 patients. (9) The review emphasized three main outcomes: change in limb circumference, change in volume, and change in annual infectious episodes. Notably, 92% of reported cases were secondary lymphedema, and 58% of these were due to breast cancer. The meta-analysis included 29 studies that reported % change in excess circumference, covering VLNT (n=20), LVA (n=8), and combined approaches (n=1), totaling 1,002 patients. The pooled results showed a -35.6% reduction in excess circumference (95% confidence interval [CI], -30.9 to -40.3%), a -32.7% reduction in excess volume (95% CI, -19.8 to -45.6%) across 12 studies (n=587 patients), and a decrease of 1.9 episodes of cutaneous infections per year (95% CI, -1.4 to -2.3) in 8 studies (n=248 patients). All studies were non-randomized, and heterogeneity was high regarding measurement units, methods, and sites. The authors highlighted ongoing large randomized and case-control studies, which are expected to further clarify efficacy and standardize outcome measurements for both techniques.

Lilja et al. (2024) conducted a systematic review on three surgical interventions for BCRL: LVA, VLNT, and liposuction. The review included 73 studies with a total of 2,373 patients, published up to June 2023. (10) Eligible studies comprised RCTs, non-randomized comparative studies, and observational designs, focusing on outcomes such as arm volume reduction, lymphatic flow, and patient quality of life. Due to significant methodological and outcome heterogeneity, no meta-analysis was performed. Findings indicated that LVA has a variable success rate, with some studies reporting reduction in limb volume and symptom relief, especially at early stages of lymphedema. VLNT was associated with promising improvements in limb volume and symptoms in mild to moderate cases. However, the overall lack of high-quality clinical evidence highlights the need for further rigorous studies to establish the efficacy of these surgical treatments for BCRL. The overlap between the primary studies included in the systematic reviews for LVA and VLNT are shown in Appendix Table 1 and Appendix Table 2.

In February 2025, a protocol for a Cochrane Review was published to evaluate the effectiveness of microsurgical procedures (including LVA and VLNT) compared to complex physical decongestive therapy (CDT) in individuals with chronic BCRL. (11) The review seeks to directly compare these two treatment modalities and offer evidence-based guidance for managing BCRL.

Randomized Controlled Trials

A protocol for the multicenter LYMPH RCT (NCT05890677) was published in February 2025. (12) This superiority trial evaluates whether adding microsurgery (LVA or VLNT) to CDT improves quality of life and outcomes for chronic BCRL compared to CDT alone, with a primary endpoint at 15 months. The study will enroll 280 patients across more than 20 sites in Europe, the U.S., Canada, and Latin America. The trial is expected to be completed in June 2036 (refer to Table 3. Summary of Key Trials).

Interim results of an ongoing multicenter RCT (NCT02790021) in women with BCRL were published by Jonis et al. (2024). (13) One hundred women with Stage 1 or 2a lymphedema were randomized to LVA surgery or conservative treatment, and 92 were included in the interim analysis. The primary outcome was quality of life as measured by the Lymphedema Functioning Disability and Health (Lymph-ICF) questionnaire. Total ICF scores improved in both groups at 6 months ([-8.57; 95% CI, -15.69 to 1.45] and [-2.65; 95% CI, -8.26 to 2.95]) in the LVA and conservative groups, respectively. However, the results were not statistically significant. There was no significant volume reduction in either group from baseline. No firm conclusions can be made pending final results of the trial (refer to Table 3. Summary of Key Trials).

Dionyssiou et al. (2016) reported on a RCT that evaluated VLNT plus physical therapy versus physical therapy alone for lymphedema in 36 women with stage II BCRL. (14) At 18 months, the reduction in the excess volume of the affected limb as a percentage of the intact limb was 57% in the VLNT group and 18% in the physical therapy group (treatment effect not reported, $p<.001$). The mean number of lymphedema-related infections per patient per year was lower in the VLNT group (0.28 vs. 1.16; treatment effect not reported, $p=.001$). The trial had several limitations. Notably, there was no description of allocation concealment, and the trial was not blinded, possibly introducing both selection and ascertainment bias. The reporting did not describe the power calculations or justify a clinically important difference for the reported outcomes. The trial was not registered, so selective reporting cannot be ruled out.

Section Summary: Physiologic Microsurgery to Treat Lymphedema

Two recent systematic reviews have examined microsurgical interventions for lymphedema, especially LVA and VLNT. Both reviews emphasize the need for higher-quality, standardized research to better assess surgical efficacy in lymphedema treatment. An ongoing RCT of LVA was identified, but analyses of comparative outcomes between groups are limited at this time. One RCT of VLNT with 36 participants has been conducted. However, these studies are not adequate for determining the comparative efficacy of physiologic microsurgery versus conservative treatment or decongestive therapy, or the comparative efficacy of different microsurgery techniques. An ongoing multi-center international RCT and the upcoming

Cochrane Review address the need for high-quality evidence to compare the efficacy of microsurgery compared to complex physical decongestive therapy for chronic BCRL. This trial is expected to provide robust evidence on the benefits of combining microsurgery with CDT compared to CDT alone. The Cochrane Review will synthesize existing and future research to offer a comprehensive understanding of the current evidence, informing clinical practice and guiding future research directions in this field.

Physiologic Microsurgery to Prevent Lymphedema

Clinical Context and Therapy Purpose

The purpose of lymphatic physiologic microsurgery simultaneous to lymphadenectomy for breast cancer (i.e., the Lymphatic Microsurgical Preventing Healing Approach [LYMPHA]) is to prevent lymphedema in individuals who are being treated for breast cancer. While recommendations on preventive measures for lymphedema exist, such as avoiding needle sticks, limb constriction, and air travel, most recommendations are based on clinical opinion. A systematic review of preventive measures for lymphedema by Cemal et al. (2011) found strong scientific evidence only for the recommendations to maintain a normal body weight or avoid weight gain and to participate in a supervised exercise regimen. (15)

LYMPHA is a preventive LVA procedure performed during nodal dissection or reconstructive surgery that involves anastomosing arm lymphatics to a collateral branch of an axillary vein.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are undergoing a lymphadenectomy or breast reconstruction procedure for breast cancer.

Interventions

This review focuses on a physiologic microsurgical intervention called LYMPHA.

Comparators

LYMPHA could be used as an adjunct to standard care. Standard care may involve education regarding lymphedema and recommendations for hygiene, avoidance of blocking the flow of fluids in the body, maintaining a normal body weight and exercise, as well as surveillance for lymphedema during follow-up with referral as needed.

Outcomes

Outcomes of interest include diagnosis of lymphedema, lymphedema symptoms, quality of life, and operative and postoperative complications. As discussed, the diagnosis of lymphedema is based on history and physical examination (localized, progressive edema, asymmetric limb measurements). There is no universal agreement on measurement criteria for asymmetric limbs. It may be quantified by a 2 or more centimeters difference in limb girth, a 200 mL difference in limb volume, or a 10% limb volume change from baseline. (16, 17) Patient reports of heaviness or swelling, either "now" or "in the past year" may also be used to suggest

lymphedema. The estimated incidence of lymphedema varies by the measurement criteria used. (17)

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Because multiple systematic reviews of studies were available for both classes of microsurgery, the focus is on systematic reviews published in 2015 or later.

Systematic Reviews

Carvalho Silva et al. (2025) conducted a meta-analysis on the efficacy and safety of immediate lymphovenous anastomosis (ILA) in breast cancer. (18) Eighteen studies published through May 2024 were included, comprising 47,645 patients from 2 RCTs and 16 nonrandomized cohorts. A total of 1401 (2.9%) patients underwent ILA and were assessed for outcomes compared to a control group that did not undergo ILA. Fifteen studies (2 RCTs and 13 observational studies) were included in the meta-analysis. In the pooled ILA group, 98 of 1026 patients (9.6%) developed lymphedema, in contrast to 584 of 1405 patients (41.6%) in the control group, demonstrating a protective effect of ILA on BCRL rate (risk ratios [RR] 0.35, 95% CI, 0.27 to 0.47; $p<.001$; $I^2=30\%$) and yielding a number needed to treat of 3.4. Moderate heterogeneity could be explained by methodological differences related to control selection, differences in BCRL diagnostic criteria between the ILA and control groups, and uneven distribution of clinical characteristics with potential confounding power, such as age, BMI, adjuvant radiation therapy/chemotherapy rates, and smoking status. Nonetheless, the subgroup analysis, including only RCTs (n=2), showed protective effect of ILA in BCRL rates without heterogeneity (0.25; 95% CI, 0.14 to 0.26; $p<.00001$; $I^2=0\%$). Subgroup analysis comparing prospective and retrospective studies showed similar results, with high heterogeneity among retrospective studies.

Another meta-analysis of 10 studies (N=1487 patients) by Wong et al. (2025) revealed that in the immediate lymphatic reconstruction (ILR) group, 50 of 637 (7.85%) patients developed BCRL whereas in the control group, 177 of 850 patients (20.8%) developed BCRL. (19) Patients treated with ILR in this analysis had a RR of 0.31 (95 % CI, 0.19 to 0.51) for developing BCRL when compared to the controls ($p<.0001$).

The overlap between the primary studies included in the systematic reviews is shown in Appendix Table 3. These reviews show that ILA has a protective effect on BCRL rates in patients undergoing ALND. However, a notable absence of rigorous clinical trials and studies with

extended follow-up limits the strength of these findings. The risk of bias assessment underscores this concern; selection and reporting bias remain prevalent across much of the current literature. To advance the field, future research must prioritize well-designed studies that both identify patient subgroups most likely to benefit from ILA and elucidate its long-term impact on cancer recurrence.

Randomized Controlled Trials

The above systematic reviews included 2 RCTs on surgical prevention of BCRL. (20, 21) No new RCTs were identified that have been published since the above systematic reviews.

Boccardo et al. (2011) reported on results of a RCT including 46 women referred for axillary dissection for breast cancer treatment between 2008 and 2009 who were randomized to LYMPHA or no preventive surgery (control). (20) All LVA procedures were performed by the same surgeon, reported to be skilled in lymphatic microsurgery. The LVA surgeon was not the same surgeon who performed lymph node dissection. The same axillary dissection treatment was performed in the 2 treatment groups. Lymphedema was diagnosed as a difference in excess volume of at least 100 mL compared with preoperative volume measurements. Lymphedema was diagnosed in 1 (4%) woman in the LYMPHA group and 7 women (30%) in the control group by 18 months of follow-up. The change in volume with respect to baseline was reportedly higher in the control group than in the LYMPHA group at 1, 3, 6, 12, and 18 months (all $p<.01$). The trial had several limitations. Notably, the follow-up duration was only 18 months. Methods of randomization and allocation concealment were not described and there was no justification of the sample size. The patients and investigators were not blinded (i.e., no sham procedure was performed) and there was no discussion of whether outcome assessors were blinded. There is no indication that the trial was registered. Coriddi et al. (2023) reported on interim results of a RCT (NCT04241341) in 144 women with breast cancer undergoing axillary lymph node dissection. (21) Women were randomized to immediate lymphatic reconstruction with lymphatic anastomosis to a regional vein or control. At the time of interim analysis only 40 individuals had the full 24-month follow-up, and interim results were reported for 99 women who had completed 12 months of follow-up. The major limitations of this report include the preliminary status of the results, the small sample size, and the single-center design.

Nonrandomized or Observational Studies

Jakub et al. (2024) conducted a prospective, two-site pragmatic trial to evaluate lymphedema rates in breast cancer patients treated by ALND, with or without ILR. (22) Among 230 patients, 99 received ALND alone and 131 were planned for ALND with ILR. Of these, 115 (88%) actually underwent ILR, performed either by a breast surgical oncologist (63%) or fellowship-trained microvascular plastic surgeons (37%). On univariable analysis, ILR was linked to higher lymphedema risk, defined as ≥10% limb volume change, but this was not significant after multivariable adjustment. No significant differences in limb volume or lymphedema grade were found between the groups, even when including subclinical lymphedema (≥5% volume change). When lymphedema was measured by patient self-reporting, provider documentation, and ICD-10 codes as a binary outcome, the rates did not differ significantly between the ILR and non-ILR cohorts.

Section Summary: Physiologic Microsurgery to Prevent Lymphedema

Two recent systematic reviews have examined microsurgical interventions for lymphedema prevention. These reviews show that immediate lymphatic reconstruction has a protective effect on breast cancer-related lymphedema rates in patients undergoing autologous lymph node transplantation. However, a notable absence of rigorous clinical trials and studies with extended follow-up limits the strength of these findings. The risk of bias assessment underscores this concern; selection and reporting bias remain prevalent across much of the current literature. One RCT including 46 women has been conducted. The trial reported that lymphedema developed in 4% of women in the LYMPHA group and 30% in the control group by 18 months of follow-up. However, because the cumulative incidence of lymphedema after breast cancer treatment approximates 30% at 3 years, longer follow-up is needed to assess the durability of the procedure. The trial methods of randomization and allocation concealment were not described and there was no blinding, potentially introducing bias. The remaining evidence consists of uncontrolled studies and systematic reviews of these studies. An ongoing RCT indicated improved lymphedema at 24 months (n=40) with immediate lymphatic reconstruction compared with controls (9.5% vs. 32%; p=.014), but conclusions based on this RCT are pending final analysis.

Summary of Evidence

For individuals who have breast cancer-related secondary lymphedema who receive physiologic microsurgery to treat lymphedema along with continued conservative therapy, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, health status measures, quality of life, resource utilization, and treatment-related morbidity. Several physiologic microsurgeries have been developed; examples include lymphaticovenular anastomosis (LVA) and vascularized lymph node transfer (VLNT). Two recent systematic reviews have examined microsurgical interventions for lymphedema, especially LVA and VLNT. Both reviews emphasize the need for higher-quality, standardized research to better assess surgical efficacy in lymphedema treatment. An ongoing RCT of LVA was identified, but analyses of comparative outcomes between groups are limited at this time. One RCT of VLNT with 36 participants has been conducted. However, these studies are not adequate for determining the comparative efficacy of physiologic microsurgery versus conservative treatment or decongestive therapy, or the comparative efficacy of different microsurgery techniques. An ongoing multi-center international RCT and the upcoming Cochrane Review address the need for high-quality evidence to compare the efficacy of microsurgery compared to complex physical decongestive therapy for chronic breast cancer-related lymphedema (BCRL). This trial is expected to provide robust evidence on the benefits of combining microsurgery with CDT compared to CDT alone. The Cochrane Review will synthesize existing and future research to offer a comprehensive understanding of the current evidence, informing clinical practice and guiding future research directions in this field. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing lymphadenectomy for breast cancer who receive physiologic microsurgery to prevent lymphedema, the evidence includes an RCT, an ongoing RCT, observational studies, and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Lymphatic Microsurgical Preventing Healing Approach (LYMPHA) is a preventive lymphaticovenular anastomosis performed during nodal dissection. Two recent systematic reviews have examined microsurgical interventions for lymphedema prevention. These reviews show that immediate lymphatic reconstruction has a protective effect on breast cancer-related lymphedema rates in patients undergoing autologous lymph node transplantation. However, a notable absence of rigorous clinical trials and studies with extended follow-up limits the strength of these findings. The risk of bias assessment underscores this concern; selection and reporting bias remain prevalent across much of the current literature. One RCT including 46 women has been conducted. The trial reported that lymphedema developed in 4% of women in the LYMPHA group and 30% in the control group by 18 months of follow-up. However, because the cumulative incidence of lymphedema after breast cancer treatment approximates 30% at 3 years, longer follow-up is needed to assess the durability of the procedure. The trial methods of randomization and allocation concealment were not described and there was no blinding, potentially introducing bias. The remaining evidence consists of uncontrolled studies and systematic reviews of these studies. An ongoing RCT indicated improved lymphedema at 24 months (n=40) with immediate lymphatic reconstruction compared with controls (9.5% vs. 32%; p=.014), but conclusions based on this RCT are pending final analysis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Association of Plastic Surgeons

The American Association of Plastic Surgeons sponsored a conference to create consensus statements and recommendations for surgical treatment and prevention of upper and lower extremity lymphedema. (23) The recommendations were based on the results of a systematic review and meta-analysis (reviewed in the Rationale section). The relevant recommendations include:

"There is evidence to support that lymphovenous anastomosis can be effective in reducing severity of lymphedema (grade 1C). There is evidence to support that vascular lymph node transplantation can be effective in reducing severity of lymphedema (grade 1B). Currently, there is no consensus on which procedure (lymphovenous bypass versus vascular lymph node transplantation) is more effective (grade 2C). A few studies show that prophylactic lymphovenous bypass in patients undergoing extremity lymphadenectomy may reduce the incidence of lymphedema (grade 1B). More studies with longer follow-up are required to confirm this benefit."

American Society of Breast Surgeons

The American Society of Breast Surgeons (ASBrS) published recommendations from an expert panel on preventive and therapeutic options for BCRL in 2017. (24) The document stated that

"the Panel agrees that LVA [lymphaticovenular anastomosis] and VLNT [vascularized lymph node transfer] may be effective for early secondary breast cancer-related lymphedema."

In a 2022 consensus statement the ASBrS stated that "newer surgical techniques, such as axillary reverse mapping, lymphatic transfer, and lympho-venous anastomosis are promising both for prevention and for treatment of established lymphedema. However, well-designed prospective studies with uniform criteria for patient selection, procedure, and outcome assessment are needed. In institutions where these techniques are available, they should be considered whenever ALND is required." (25)

International Society of Lymphology

The International Society of Lymphology published an updated consensus document on the diagnosis and treatment of peripheral lymphedema in 2023. (26)

The document stated the following on LVA and VLNT:

- "Lymphaticvenous (or lymphovenous) anastomoses (LVA) are currently in use at many centers around the world. These procedures have undergone confirmation of long-term patency (in some cases more than 25 years) and demonstration of improved lymphatic transport (by objective physiologic measurements of long-term efficacy). Multiple lymphatic-venous anastomoses in a single surgical site, with both the superficial and deep lymphatics, allow the creation of a positive pressure gradient (lymphatic-venous) and evade the phenomenon of gravitational reflux without interrupting the distal peripheral superficial lymphatic pathways. Some centers particularly in areas of endemic filariasis also practice lymph nodal-venous shunts as a derivative method. Multiple centers are using LVA (LYMPHA technique) as a preventative measure in high-risk patients with good results although there has been one report concluding no long-term (4-year) effect."
- "Vascularized Lymph Node Transplantation. Transplantation of superficial lymph nodes (often using microsurgical techniques) from an uninvolved area together with the vascular supply (VLNT) to the site of lymphadenectomy is performed in multiple centers. Studies have been performed in these centers to generally support the efficacy of these operations...VLNT procedures have been shown to improve patient outcomes in several studies, but the effect may also depend on pronounced scar release in the axilla increasing the venous outflow in patients with breast cancer-related lymphedema as well as using postoperative compression garments. More work is needed in this area with increased standardization of procedures to develop a stronger experience and there is further documentation to clearly depict changes in the lymphatic system and potential increase in transport of lymph to and through these nodes/flaps. These studies need to include volume decrease as well as QOL investigations."

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) published recommendations on management of lymphedema as part of its guideline on survivorship (Version 2.2025); however, it does not discuss physiologic microsurgical techniques. (27) The guideline states that high-level evidence in support of treatments for lymphedema is lacking. In addition, the NCCN

guideline on breast cancer does not give recommendations on use of physiological microsurgical techniques for preventing or treating lymphedema (Version 5.2025). (28)

National Lymphedema Network

The National Lymphedema Network (NLN) published a position paper on the diagnosis and treatment of lymphedema in 2011. (29) The paper provided the following statements, although notably, the document has been retracted, and the Network is currently in the process of drafting a new position statement:

- "Microsurgical and supramicrosurgical (much smaller vessels) techniques have been developed to move lymph vessels to congested areas to try to improve lymphatic drainage. Surgeries involve connecting lymph vessels and veins, lymph nodes and veins, or lymph vessels to lymph vessels. Reductions in limb volume have been reported, and a number of preliminary studies have been done, but there are no long-term studies of the effectiveness of these techniques."

According to their website, the NLN identifies four surgical approaches for treatment: lymphatic debulking procedures, excisional surgeries, VLNT, and LVA. (30)

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 3.

Table 3. Summary of Key Trials

NCT Number	Trial name	Planned Enrollment	Completion Date
NCT05890677	The LYMPH Trial - Comparing Microsurgical With Conservative Treatment of Chronic Breast Cancer Associated Lymphedema: Study Protocol of a Pragmatic Randomized International Multicentre Superiority Trial	280	Jun 2036
NCT04687956	Effect of Lymphatic Microsurgical Preventing Healing Approach (LYMPHA) for Primary Surgical Prevention of Breast Cancer-related Lymphedema	72	Dec 2027 (last update posted Oct 2023)
NCT05064176	Comparison of Reconstructive Lymphatic Surgery Versus no Surgery, Additional to Decongestive Lymphatic Therapy (Usual Care), for the Treatment of lymphoedema, Through a Multicentre Randomised Controlled Trial	180	Dec 2026
NCT03428581	Preventing Lymphedema in Patients Undergoing Axillary Lymph Node Dissection Via Axillary Reverse Mapping and Lympho-venous Bypass	264	Feb 2026

NCT04241341	A Randomized Controlled Trial: Does Immediate Lymphatic Reconstruction Decrease the Incidence of Lymphedema After Axillary Lymph Node Dissection	180	Jan 2026
NCT03941756	Prophylactic Lymphovenous Bypass Procedure Following Axillary Lymphadenectomy: A Prospective Observational Study	252	Dec 2025
NCT02790021	Improving the Quality of Life of Patients With Breast Cancer-related Lymphedema by Lymphaticovenous Anastomosis (LVA): A Randomized Controlled Trial	100	Jan 2025
NCT04579029	Prospective Randomized Evaluation of Lymphaticovenous Anastomosis Using Dynamic Imaging in Breast Cancer-related Lymphoedema	64	Apr 2024 (last update posted: Jan 2023)

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	15756, 15758, 15830, 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, 15847, 38308, 38589, 38999, 49906, 1019T, 1081T, 1082T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/15/2025	Document updated. Coverage unchanged. Added reference 9-13, 18, 19, 22, 25, 26 and 30; some updated and others removed.
05/15/2025	Document updated with literature review. The following changes were made to Coverage: 1) Removed content related to suction assisted protein lipectomy for lipedema and lymphedema, which will now be addressed on SUR708.003; 2) Removed content related to reverse lymphatic mapping, which will now be addressed on SUR708.002; and 3) Changed "Surgery for prevention or treatment of lymphedema (e.g., microsurgical lymphovenous anastomoses or vascularized lymph node transfer) is considered experimental, investigational and/or unproven" to "Lymphatic physiologic microsurgery to treat lymphedema (including, but not limited to, lymphatico-lymphatic bypass, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node transplantation, and vascularized lymph node transfer) in individuals who have been treated for breast cancer is considered experimental, investigational and/or unproven. Lymphatic physiologic microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach) in individuals who are being treated for breast cancer is considered experimental, investigational and/or unproven." Added new references 2-5, 13, and 30; others removed and some updated.
02/01/2024	Document updated with literature review. Coverage unchanged. Added/updated the following references: 2-4, 6, 8-10, 12, 13, 27, 38, 53-73, 80-82, and 84.
02/01/2023	Reviewed. No changes.
04/01/2022	Document updated with literature review. The following changes were made to Coverage: 1) Added "including any subsequent revisions" to the suction assisted protein lipectomy for the treatment of lipedema medically necessary statement; 2) Added an experimental, investigational and/or unproven statement for reverse lymphatic mapping; and 3) Added NOTE 4: This policy does not address abdominal procedures, refer to SUR716.001 Cosmetic and Reconstructive Procedures for specific language on abdominal procedures, including but not limited to, panniculectomy and suction assisted lipectomy. References 10, 15, 18, 24, 52 and 53 were added and others updated.

04/01/2021	Reviewed. No changes.
11/15/2020	Document updated with literature review. The following change was made to Coverage: Added conditional criteria for suction assisted protein lipectomy for the treatment of lipedema. Added references 1-2, 4-8, 42-47 and 49. Title changed from Surgery for Lymphedema.
02/15/2020	Document updated with literature review. The following changes were made to Coverage: 1) Prevention or treatment was added to the Surgery for Lymphedema experimental, investigational and/or unproven statement. 2) Suction assisted protein lipectomy (also known as suction lipectomy and liposuction) is considered experimental, investigational and/or unproven for lymphedema, including but not limited to as a result of treatment for melanoma was added. 3) NOTE 2: For suction assisted lipectomy in reconstructive and contralateral mammaplasty see medical policy SUR716.011 was added. 4) NOTE 3: For the use of liposuction in reduction mammoplasty see medical policy SUR716.012 was added. References 1-10, 12-21, and 27-37 were added and some references removed.
04/15/2017	Document updated with literature review. The following change was made to the Coverage Section: A NOTE was added that states "See SUR716.001 Cosmetic and Reconstructive Procedures for CoolSculpting (may also be known as cryolipolysis or fat freezing)."
04/15/2016	Document updated with literature review. Coverage unchanged.
10/01/2015	Reviewed. No changes.
12/01/2014	Document updated with literature review. The following example has been added to the coverage statement: vascularized lymph node transfer. CPT/HCPCS code(s) updated.
02/01/2012	Document updated with literature review. Coverage unchanged.
11/15/2010	Document updated with literature review. Coverage unchanged. CPT code added.
07/01/2009	New medical document

Appendix

Appendix Table 1. Comparison of Studies Included in Systematic Reviews of Lymphedema Surgeries Using the Venous System (LVA)

	Meuli et al. (2023) (9)	Lilja et al. (2024) (10)
Roh et al. (2023)		●
Ciudad et al. (2023)		●
Fuse et al. (2022)		●
Park et al. (2022)		●
van Mulken et al. (2022) (RCT)		●
Visconti G et al. (2022)		●

Rodriguez et al. (2022)		●
Boccardo et al. (2022)		●
Brahma et al. (2021)		●
Kim et al. (2021)	●	
Yodrabum et al. (2021)	●	
Wolfs et al. (2020)		●
Qiu et al. (2020)		●
Seki et al. (2019)		●
Winters et al. (2019)		●
Phillips et al. (2019)		●
Khan AA et al. (2019)		●
Mihara M et al. (2018)		●
Engel et al. (2018)	●	
Poumellec et al. (2017)		●
Cornelissen et al. (2017)		●
Winters et al. (2017)		●
Gennaro et al. (2016)	●	●
Ito et al. (2016)	●	
Chang et al. (2013)		●
Ayestaray et al. (2013)		●
Mihara et al. (2012)		●
Chang et al. (2010)		●
Damstra et al. (2009)		●
Koshima et al. (2004)	●	
Koshima et al. (2003)	●	
Koshima et al. (2000)	●	
Koshima et al. (1996)	●	

LVA: lymphaticovenular anastomosis.

Appendix Table 2. Comparison of Studies Included in Systematic Reviews of Lymphedema Surgeries Using Lymph Tissue Transfer (VLNT)

	Meuli et al. (2023) (9)	**Lilja et al. (2024) (10)**
Agko et al. (2018)		
Aljaaly et al. (2019)		
Cheng et al. (2013)	●	●
Cheng et al. (2012)		
Ciudad et al. (2020)	●	●
Ciudad et al. (2017)		
Di Taranto et al. (2020)		
Gustafsson et al. (2018)		
Ho et al. (2019)		
Ho et al. (2018)	●	●

Lin et al. (2009)	●	●
Liu et al. (2018)	●	●
Maruccia et al. (2019a, 2019b)	●	●
Patel et al. (2015a, 2015b)	●	
Roka-Palkovits et al. (2021)	●	
Viitanen et al. (2013)	●	
Dionyssiou et al. (2016)		●
Becker et al. (2006)		●
Abdelfattah et al. (2021)		●
Ciudad et al. (2023)		●
Engel et al. (2018)		●
Aljaaly et al. (2019)		●
Lin et al. (2020)		●
Francis et al. (2022)		●
Patel et al. (2015)		●
Brown et al. (2022)		●
Gratzon et al. (2017)		●
Nguyen et al. (2015)		●
Chang et al. (2020)		●
Yang et al. (2017)		●
Winters et al. (2022)		●
Rannikko et al. (2021)		●
Dionyssiou et al. (2021)		●
Mousavi et al. (2020)		●
Arriv et al. (2017)		●
De Brucker et al. (2016)		●
Akita et al. (2017)		●
Ngo et al. (2020)		●
Montag et al. (2019)		●
Di Taranto et al. (2023)		●
Akita et al. (2022)		●

VLNT: vascularized lymph node transfer.

Appendix Table 3. Comparison of Studies Included in Systematic Reviews of LYMPHA to Prevent Lymphedema

	Carvalho Silva et al. (2025) (18)	**Wong et al. (2025) (19)**
Coriddi et al. (2023) (RCT)	●	●
Boccardo et al. (2011) (RCT)	●	●
Haravu et al. (2024)	●	
Le et al. (2024)	●	

Ovchinnikova et al. (2024)	●	
Wong et al. (2024)		●
Chung et al. (2023)		●
Deldar et al. (2023)	●	●
Le et al. (2023)	●	●
Levy et al. (2023)	●	●
Ozmen et al. (2022)	●	
Ozmen et al. (2018)		●
Weinstein et al. (2022)	●	
Herremans et al. (2021)	●	●
Johnson et al. (2021)	●	
Cakmakoglu et al. (2020)	●	
Hahamoff et al. (2019)	●	
Feldman et al. (2015)	●	●

LYMPHA: Lymphatic Microsurgical Preventing Healing Approach.